

K964865

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510(k) Summary

Submitter's Name: Toshiba America Medical Systems, Inc.
Submitter's Address: P.O. Box 2068, 2441 Michelle Drive, Tustin CA 92781-2068
Submitter's Contact: Steven M. Kay, Regulatory Affairs Specialist, (714) 730-5000
Establishment Registration Number: 2020563

Device Proprietary Name: PVK-720ST Endocavitary Transducer
Common Name: Diagnostic Ultrasound Transducer
[Fed. Reg. No.: 892.1570, Pro. Code: 90-ITX]

Regulatory Class: II
514 Performance Standards: None
Special Controls: None
Prescription Status: Prescription Device

Reason for Submission:
Modification of the SSA-380A

Substantial Equivalence Summary:

The PVK-720ST Endocavitary Transducer will be used with the SSA-380A diagnostic ultrasound system, which was cleared for cardiac, fetal, small organ and peripheral vascular applications in K933743 and abdominal organ imaging in K943303. The SSA-380A system software and hardware is only upgraded to recognize the addition of the PVK-720ST Endocavitary Transducer. No other system changes were required. The PVK-720ST Endocavitary Transducer is similar to the PVE-582V endocavitary transducer that was cleared for transvaginal use with the SSA-270A diagnostic ultrasound system in K891453.

The PVK-720ST follows the same software verification and validation procedures and employs the same general technology as that previously cleared for the SSA-380A system in K933743. It does not affect cleared patient contact materials or acoustic output intensities. Based on a review of TAMS Complaint and MDR files for similar transducers, any potential failure of this transducer is not expected to result in an injury to the patient.